PATENT
Customer No. 22,852
Attorney Docket No. 08178.0031-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Yoshio MIKI et al.	)	Group Art Unit: 1634
	)	
Application No.: 10/578,077	)	Examiner: Diana B. JOHANNSEN
	)	
§371(c) Date: May 8, 2007	)	
International Filing Date: November 5, 2004	)	
	)	
For: METHOD AND KIT FOR PREDICTING ADVERSE SIDE EFFECTS OF PACLITAXEL THERAPY	)	Confirmation No. 3057

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

Applicants now respond to the Office Action mailed September 21, 2009, the period for response having been extended to November 21, 2009, by a Petition for One Month Extension of Time and fee payment filed concurrently herewith.

The Office required restriction between the following groups of claims under 35 U.S.C. § 121:

> Group I: Claims 1-9, allegedly drawn to methods for predicting risk of granulocytopenia; and
>
> Group II: Claims 10-16, allegedly drawn to a kit comprising a reagent for identifying polymorphisms.

Applicants provisionally elect to prosecute Group I, claims 1-9, **with traverse**.

The Office contends that Reeve et al. (International Application No. WO9947706A1) ("Reeve") teach kits that may include arrays comprising all possible "N mer" oligonucleotide or subsets thereof "where N is preferably from 5 to 10, particularly 8 or 9." Office Action at 2. The Office also contends that Reeve discloses the use of their reagents in "determining the difference between target and reference sequences." *Id.* Thus, the Office concludes, "Groups I-II lack unity of invention." *Id.*

Applicants respectfully traverse. Reeve does not teach or suggest a kit for predicting the risk of the occurrence of granulocytopenia caused by paclitaxel therapy in a subject comprising a reagent for identifying in a gene isolated from the subject one or more genetic polymorphisms in the CYP2C8 gene or the BUB1b gene. While Reeve discloses an array of "N mers," where "N is preferably from 5 to10, particularly 8 or 9" (*see* page 5, lines 9-11), Reeve does not disclose the genetic polymorphisms in the two genes CYP2C8 and BUB1b, as defined in independent claim 10, let alone a kit for detecting these genetic polymorphisms. Nor does Reeve teach or suggest any connection of the genetic polymorphisms in those two genes to the risk of the occurrence of granulocytopenia caused by paclitaxel therapy. Therefore, Applicants respectfully submit that Reeve does not disclose a product meeting the requirements of Group II. For at least this reason, Reeve does not defeat unity of invention of Groups I-II.

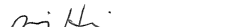
The Office also issued a species election requirement. Applicants elect to prosecute the following species: a genetic polymorphism at the 11th nucleotide of the sequence defined by SEQ ID NO: 6 in BULB1b gene. As requested, Applicants identify claims 1 and 4-9 as readable on the elected species.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: October 28, 2009

By: 

Bing Hai
Reg. No. 57,170
(650) 849-6774